

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Nested Bean, Inc.,

Plaintiff,

v.

U.S. Consumer Product Safety
Commission, *et al.*,

Defendants.

Case No. 1:25-cv-00389-RGA

Memorandum in Support of Defendants' Motion to Dismiss

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NATURE AND STAGE OF THE PROCEEDINGS

On March 28, 2025, Nested Bean, Inc. filed a seven-count Complaint against Defendants, which include four federal agencies. Specifically, the Complaint asserts (a) three Administrative Procedure Act (“APA”) claims against the U.S. Consumer Product Safety Commission (“CPSC” or “Commission”); (b) *ultra vires* and due process claims against a former member of the Commission, Richard Trumka¹; (c) a constitutional challenge to the Consumer Product Safety Act; and (d) an *ultra vires* claim against the Department of Health and Human Services (“HHS”), the Centers for Disease Control and Prevention (“CDC”), and the National Institutes of Health (“NIH”). The Complaint also nominally names as Defendants seven individuals who serve or served at CPSC, HHS, CDC, or NIH.

Defendants now move to dismiss the Complaint under Federal Rules of Civil Procedure 12(b)(1) and (b)(6).

SUMMARY OF THE ARGUMENT

CPSC provides the public with educational resources about the risks of injury associated with various consumer products. Nested Bean challenges a CPSC recommendation against the use of weighted infant blankets and swaddles, which was based on similar recommendations made by CDC and NIH. After CPSC added this advice to its website in 2023, a now former Commissioner, Richard Trumka, expressed

¹ After the Complaint was filed, President Trump removed three CPSC Commissioners, including Richard Trumka, from office. *See Trump v. Boyle*, 145 S. Ct. 2653 (2025).

his individual view that weighted infant sleep products are unsafe through statements on social media and in letters to retailers.

Nested Bean makes and sells weighted infant sleep products. Nested Bean disagrees with CPSC's safe sleep recommendation about weighted infant sleep products and former Commissioner Trumka's individual actions. In November 2024, Nested Bean requested that the Commission retract both the guidance on its website and former Commissioner Trumka's statements. The Commission deadlocked on whether to grant or deny the request.

Nested Bean now sues CPSC, former Commissioner Trumka, HHS, CDC, and NIH. Counts I, IV, and V assert APA claims, challenging CPSC's guidance about weighted infant sleep products and the deadlocked vote on Nested Bean's retraction request. However, neither the guidance nor the deadlocked vote constitutes a final agency action reviewable under the APA. Even if they did, Nested Bean's conclusory and unsupported allegations do not plausibly show that, by providing non-binding safety recommendations to the public, CPSC exceeded its statutory authority, acted arbitrarily or capriciously, or failed to observe required procedures.

Nested Bean's *ultra vires* claims against HHS, CDC, and NIH (Count II), and against former Commissioner Trumka (Count III) are no more availing. The agencies have clear statutory authority to make safety recommendations to the public. And former Commissioner Trumka's statements were permissible because they repeated CPSC's (also permissible) guidance and did not run afoul of statutory requirements that apply when a CPSC statement identifies an individual company.

Finally, Nested Bean's due process claim against former Commissioner Trumka (Count VI) and constitutional challenge to the Commissioners' for-cause removal protections (Count VII) are meritless. Nested Bean merely speculates about harm it might suffer from former Commissioner Trumka's alleged bias or the statutory removal protections. Such speculation will not suffice for jurisdiction or a plausible claim.

For all these reasons, the Complaint should be dismissed in its entirety.

BACKGROUND

I. Legal background

A. CPSC's authority to publicly disclose information about consumer products

Congress established CPSC to, among other missions, "protect the public against unreasonable risks of injury from consumer products," "assist consumers in evaluating the comparative safety of consumer products," and "develop uniform safety standards for consumer products." 15 U.S.C. §§ 2051(b)(1)-(3), 2053(a). CPSC carries out these missions under various statutory authorities, including the Consumer Product Safety Act ("CPSA"), 15 U.S.C. § 2051 *et seq.*

Relevant here are the Commission's "broad powers" under the CPSA "to gather, analyze, and disseminate vast amounts of private information." *CPSC v. GTE Sylvania, Inc.*, 447 U.S. 102, 111 (1980). Subject to certain exceptions, 15 U.S.C. § 2055 governs any disclosure of "information . . . by the Commission, any member of the Commission, or any employee, agent, or representative of the Commission in an official capacity." *Id.* § 2055(d)(2). Section 2055(b)(6) requires that CPSC "establish procedures designed to ensure" its "public disclosure of information that reflects on the safety of a consumer

product or class of consumer products . . . is accurate and not misleading.” *Id.*

§ 2055(b)(6). Those procedures are contained in Commission Directive 1450.2.² *See* 16 C.F.R. § 1101.1(c).

The CPSA also requires CPSC to retract information when it “finds that, in the administration of this Act, it has made public disclosure of inaccurate or misleading information which reflects adversely upon the safety of any consumer product or class of consumer products, or the practices of any manufacturer . . . of consumer products.” 15 U.S.C. § 2055(b)(7). Upon such a finding, the agency “shall, in a manner equivalent to that in which such disclosure was made, take reasonable steps to publish a retraction of such inaccurate or misleading information.” *Id.*; *see* 16 C.F.R. §§ 1101.1, 1101.51-1101.52.

B. CDC’s and NIH’s authority to publicly discuss infant sleep safety

The Public Health Service Act grants HHS and its subagencies, including CDC and NIH, abundant and broad authority to communicate with the public about safe infant sleep. For example, HHS and its subagencies are authorized to “disseminat[e] information to educate the public” about “sudden unexpected infant death,” 42 U.S.C. § 300c-13(a)(2), and “develop, support, or maintain programs” that address it, *id.* § 300c-11(a). The agencies are also empowered to conduct “activities” to make “health information” available to those who need it, including through “[t]he publication of information” about topics such as “child care” and “safety and accident prevention.” *Id.* § 300u-3(1). They are further authorized to “collect and make available through

² <https://perma.cc/2NV5-FXHB>.

publications and other appropriate means, information as to, and the practical application of, . . . research, investigations, experiments, demonstrations, and studies relating to the causes . . . and prevention of physical and mental diseases.” *Id.* § 241(a)(1).

II. Factual background

A. Agency statements about safe sleep

In late 2023, CPSC “modified” its “Safe Sleep” webpage “to recommend that the public not use . . . weighted infant blankets and swaddles.” Compl. ¶ 78. CPSC stated, “This guidance is based on information from the Centers for Disease Control and the National Institutes for Health. Please go to CDC.gov and NIH.gov for more information.” *Id.*

CDC and NIH also maintain webpages with “Safe Sleep guidance for the public.” *Id.* ¶ 5. A CDC webpage identifies steps to “reduce the risk of sleep-related infant deaths” and informs the public that “[p]roducts labeled as weighted—including weighted sleepers, swaddles, sleep sacks, and blankets—are not safe for infants.” CDC, *Helping Babies Sleep Safely*.³ NIH also has a webpage dedicated to creating a “safe sleep area,” which explains that “[t]hings in the sleep area can pose dangers for” babies, especially if they are “[w]eighted (e.g., weighted blankets, weighted swaddles).” NIH, *Safe Sleep Environment for Baby*.⁴

³ <https://perma.cc/5JDC-K8P5>.

⁴ <https://perma.cc/8KG9-DM53>.

B. Former Commissioner Trumka's statements

In early 2024, then-Commissioner Trumka issued several public statements, which expressed his own concern about weighted infant sleep products and advised consumers not to use them and retailers not to sell them. Compl. ¶¶ 79-86.

On January 26, 2024, Commissioner Trumka posted a message to his official X account noting CPSC's safe sleep guidance was "in agreement" with recommendations by CDC, NIH, and the American Academy of Pediatrics. *Id.* ¶ 80. The post also included a link to a Washington Post article that in turn mentioned Nested Bean and its products. *Id.* On April 15, 2024, Commissioner Trumka sent letters to several retailers advising that weighted infant sleep products are unsafe, asking them to consider not selling those products, and including a link to the Washington Post article. *Id.* ¶¶ 81, 85-86. The same day, Commissioner Trumka posted a video to his social media accounts stating his view that weighted swaddles and blankets are unsafe, and he released a statement again noting that CPSC's safe sleep guidance recommended against weighted infant sleep products. *Id.* ¶¶ 83, 84. And on April 26, 2024, Commissioner Trumka posted a video to his social media accounts stating that four retailers had decided to "cease sales of weighted infant products." *Id.* ¶¶ 85-86.

C. Nested Bean's retraction request

Nested Bean makes and sells "infant and toddler products, including weighted infant sleepwear." Compl. ¶ 9. On November 11, 2024, Nested Bean requested that CPSC retract the safe sleep guidance on the agency's website and Commissioner Trumka's statements about weighted infant sleep products. *See id.* ¶¶ 100-01. On

December 19, 2024, the Commission voted “0-1-1-2” on the retraction request—that is, “0 commissioners voting for the retraction, 1 and 1 representing separately proposed courses of action, and 2 representing two abstentions.” *Id.* ¶ 102 (citing CPSC, *Record of Commission Action* (“RCA”)⁵). Specifically, Chairman Hoehn-Saric voted “to take other action” that would “extend the time for action on the request” for “an additional 90 working days.” RCA at 1; *see* Compl. ¶ 102. Commissioner Boyle voted “to take other action” by (a) sending a letter to retailers confirming the legal status of Commissioner Trumka’s communications, and (b) directing agency staff “to review the [safe sleep guidance] in light of any” new information or data and “update the [guidance] as appropriate . . . within 45 days.” RCA at 1; *see* Compl. ¶ 102. Commissioners Feldman and Dziak abstained from the vote and issued a joint statement. Compl. ¶ 102. Commissioner Trumka voluntarily recused himself from the matter. *Id.* ¶ 102. Because “[a] majority was not reached,” the Commission took “no action” on Nested Bean’s retraction request. RCA at 1.

III. This lawsuit

On March 28, 2025, Nested Bean filed this lawsuit. Counts I, IV, and V assert APA claims against CPSC’s safe sleep guidance and the Commission’s deadlocked vote on retraction. *See* Compl. ¶¶ 103-18, 145-63. Counts II and III allege *ultra vires* claims against HHS, CDC, NIH, and former Commissioner Trumka. *Id.* ¶¶ 119-44. Count VI brings a due process claim against former Commissioner Trumka, *id.* ¶¶ 164-75, and

⁵ <https://perma.cc/2WGQ-AFFG>.

Count VII challenges the CPSA's removal protections for Commissioners, *id.* ¶¶ 176-84. Nested Bean asks this Court to declare that agencies' various statements were unlawful, former Commissioner Trumka is impermissibly biased, and the removal protections are unconstitutional, as well as to order that the agencies retract their statements and not make further statements about weighted infant sleep products. *Id.* pp. 43-44.

Defendants now move to dismiss the Complaint for lack of subject-matter jurisdiction and failure to state a claim.

LEGAL STANDARD

On a motion under Federal Rule of Civil Procedure 12(b)(1), the Court "presume[s]" to "lack jurisdiction" unless the plaintiff carries the "burden of establishing it." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3 (2006). At the pleading stage, the plaintiff "must plausibly allege all jurisdictional elements." *Brownback v. King*, 592 U.S. 209, 217 (2021).

Under Rule 12(b)(6), "only a complaint that states a plausible claim for relief survives a motion to dismiss" *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). "A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 663. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* at 678. And "if as a matter of law 'it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations,' a claim must be dismissed, without regard to whether it is based on an

outlandish legal theory or on a close but ultimately unavailing one.” *Neitzke v. Williams*, 490 U.S. 319, 326-27 (1989) (quoting *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)).

In reviewing a motion to dismiss, courts consider “the complaint in its entirety, . . . documents incorporated into the complaint by reference, and matters of which a court may take judicial notice.” *Winer Family Tr. v. Queen*, 503 F.3d 319, 328 (3d Cir. 2007) (citation omitted). The Court may take judicial notice of “information [that] is publicly available on government websites.” *Vanderklok v. United States*, 868 F.3d 189, 205 n.16 (3d Cir. 2017).

ARGUMENT

I. Counts I, IV, and V do not plausibly allege APA claims

A. Nested Bean does not challenge “final agency action”

Counts I, IV, and V raise APA claims. *See* Compl. ¶¶ 103-18, 145-63. However, “the APA does not provide judicial review for everything done by an administrative agency.” *Nat’l Veterans Legal Servs. Program v. U.S. Dep’t of Def.*, 990 F.3d 834, 839 (4th Cir. 2021) (quotation omitted). Rather, the “APA provides for judicial review only of ‘final agency action.’” *Dalton v. Specter*, 511 U.S. 462, 469 (1994) (quoting 5 U.S.C. § 704). The term “final agency action” comprises “two components – agency action and finality of agency action,” each of which “narrows the scope of judicial review.” *Nat’l Veterans Legal Servs.*, 990 F.3d at 839.

Nested Bean avers that CPSC’s safe sleep guidance, Compl. ¶ 105, and the deadlocked vote on Nested Bean’s retraction request, *id.* ¶ 28, are final agency action. But non-binding guidance and a deadlocked vote are not “agency action,” much less

“final agency action.” Counts I, IV, and V therefore “cannot state a claim under the APA.” *Chehazeh v. Att’y Gen. of U.S.*, 666 F.3d 118, 125 n.11 (3d Cir. 2012).

1. CPSC’s safe sleep guidance

No “agency action.” The Complaint does not allege CPSC’s guidance is a particular type of “agency action” under 5 U.S.C. § 551(13), and none of the few possibilities fits. Unlike an “order,” 5 U.S.C. § 551(6), the guidance is not a “a final disposition,” formulated through an “adjudication,” with “determinate consequences” for Nested Bean or anyone else, 5 U.S.C. § 551(7); *Int’l Tel. & Tel. Corp. v. Loc. 134, Int’l Bhd. of Elec. Workers*, 419 U.S. 428, 443 (1975). CPSC’s guidance does “not order anybody to do anything,” and “standing alone,” it would “bind[] no one.” *Int’l Tel. & Tel.*, 419 U.S. at 444 (quotation omitted). The same absence of any “legal effect” precludes treatment of the guidance as a “rule.” 5 U.S.C. § 551(4); *Indus. Safety Equip. Ass’n v. EPA*, 837 F.2d 1115, 1118-19 (D.C. Cir. 1988) (EPA report warning against, but not prohibiting, the use of certain asbestos-protection respirators was not a rule or other agency action). Similarly, guidance to consumers is not a “sanction” because it does not plausibly limit Nested Bean’s “freedom” or withhold relief, impose a fine, take or withhold property, assess damages, revoke any license, or take any “other compulsory or restrictive action.” 5 U.S.C. § 551(10); *see Arrow Reliance, Inc. v. Califf*, No. 2:22-cv-1057, 2022 WL 18027595, at *4 (W.D. Wash. Dec. 30, 2022) (FDA press release recommending that consumers not use plaintiff’s pet food was not sanction or other agency action).

No “final agency action.” Even if CPSC’s guidance were “agency action” within the meaning of 5 U.S.C. § 551(13), Nested Bean also must show it is “final agency

action,” *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 882 (1990). An “agency action” is “final” when it: (1) “mark[s] the consummation of the agency’s decisionmaking process”; and (2) is an action “by which rights or obligations have been determined, or from which legal consequences will flow.” *Chemours Co. FC, LLC v. EPA*, 109 F.4th 179, 184 (3d Cir. 2024) (quoting *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997)). An action must satisfy both prongs of the *Bennett* test to be final. *See id.*

Courts consistently hold that non-binding statements are not final agency action under the APA. *See, e.g., id.* at 184-85 (EPA health advisory regarding safe levels of chemical in drinking water was not final agency action); *Aerosource, Inc. v. Slater*, 142 F.3d 572, 581 (3d Cir. 1998) (FAA reports warning aviation community that the plaintiff may have improperly maintained aircraft parts were not final agency action); *Holistic Candles & Consumers Ass’n v. FDA*, 664 F.3d 940, 945 & n.6 (D.C. Cir. 2012) (collecting cases and holding that FDA warning letter was not final agency action); *Flue-Cured Tobacco Coop. v. EPA*, 313 F.3d 852, 854 (4th Cir. 2002) (EPA report classifying environmental tobacco smoke as a carcinogen was not final agency action).⁶

Nested Bean cannot satisfy the first *Bennett* prong because CPSC’s safe sleep guidance does not consummate any decisionmaking process. Nothing in the guidance committed CPSC to a “definitive” position on the lawfulness of any product or to take

⁶ Nested Bean mistakenly relies on *Apter v. Dep’t of Health & Hum. Servs.*, 80 F.4th 579 (5th Cir. 2023), to argue that agency statements “advocating for or against a particular action by the public are final agency action.” Compl. ¶ 130. *Apter* held the opposite: FDA’s recommendation that the public not use ivermectin was “not *final* agency action” because it did not “bind FDA and its staff to a legal position,” “set forth a legal standard,” or contain FDA’s definitive “view of the law.” 80 F.4th at 594.

any enforcement or regulatory action. *Hindes v. FDIC*, 137 F.3d 148, 162 (3d Cir. 1998) (quoting *FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 241 (1980)); see *Jake's Fireworks Inc. v. CPSC*, 105 F.4th 627, 632 (4th Cir. 2024) (CPSC warning notice did not consummate agency process because it “d[id] not trigger any of the administrative, civil, or criminal proceedings that the [agency] could pursue”). CPSC also has not initiated a rulemaking required to set a mandatory safety standard or ban a hazardous product. See 15 U.S.C. §§ 2056-58.

Nor did CPSC’s guidance bear the hallmarks of a final agency order: “[W]hen the Commission itself does issue orders, it says so, stating that they are ‘final decisions and orders’ to perform clearly binding commands.” *Jake’s Fireworks*, 105 F.4th at 633 (citation omitted). As such, CPSC’s guidance did not go through any of “the steps required” for it “to have any legal consequences,” and therefore it does not consummate any agency process. *Reliable Automatic Sprinkler Co. v. CPSC*, 324 F.3d 726, 732 (D.C. Cir. 2003).

Nested Bean also cannot satisfy the second *Bennett* prong because the guidance did not determine any “rights” or establish any “direct consequence for parties who choose to disregard [CPSC’s] advice.” *Chemours*, 109 F.4th at 185 (quoting *Bennett*, 520 U.S. at 178). Nested Bean does not (and could not plausibly) allege that the guidance imposes any “obligations, prohibitions, or restrictions,” *id.*, or that it “fixes some legal relationship,” *Reliable*, 324 F.3d at 731. To the contrary, Nested Bean concedes that CPSC’s guidance merely “opine[d]” on the safety of certain products, Compl. ¶ 117, and that “CPSC has not [] adopted any voluntary or mandatory product safety standard for weighted infant sleep products . . . , nor [has CPSC] issued a recall, stop sale, or ban

for Nested Bean's products," *id.* ¶ 4; *see id.* ¶ 73. CPSC thus "cannot enforce" its guidance, *Chemours*, 109 F.4th at 185, and the guidance "does not command any action," *Jake's Fireworks*, 105 F.4th at 633. And any "persua[sive]" effect on third parties, *Chemours*, 109 F.4th at 186, and "practical consequences" for Nested Bean's business, *Reliable*, 324 F.3d at 731, does not satisfy the second *Bennett* prong, *see Invention Submission Corp. v. Rogan*, 357 F.3d 452, 459 (4th Cir. 2004).

At bottom, Nested Bean has not plausibly alleged that CPSC's guidance was "agency action" and "final agency action." Thus, Counts I, IV, and V should be dismissed as to the guidance. *Chehazeh*, 666 F.3d at 125 n.11.

2. The deadlocked Commission vote

The Commission's deadlocked vote on Nested Bean's request to retract the CPSC safe sleep guidance and Commissioner Trumka's statements also is not "agency action" or "final agency action." With four Commissioners participating, "the outcome of the vote was 0-1-1-2," Compl. ¶ 102—that is, 0 votes to grant or deny the request, 1 and 1 representing votes "to take other action[s]," and 2 abstentions—resulting in "no action" on Nested Bean's request. RCA at 1.

The D.C. Circuit has squarely held that the "deadlocked vote" of a multi-member commission "cannot be considered an order of the Commission nor can it constitute agency action." *Sprint Nextel Corp. v. FCC*, 508 F.3d 1129, 1131 (D.C. Cir. 2007); *see Pub. Citizen, Inc. v. FERC*, 839 F.3d 1165, 1170 (D.C. Cir. 2016) ("FERC did not engage in collective, institutional action when it deadlocked on FCA 8's rates."). Rejecting an argument that "the deadlock had the effect of denying [the] petition," the court

explained that “the general rule that a tied vote retains the status quo” is the natural “consequence[]” of “the ‘almost universally accepted common-law rule’ that only a ‘majority of a collective body is empowered to act for the body,’” 508 F.3d at 1131-32 (quoting *FTC v. Flotill Prods., Inc.*, 389 U.S. 179 (1967)). “The votes were actions of the individual Commissioners, not the Commission,” and “[t]ies therefore do not result in Commission action.” *Id.*

Here, no majority was reached, so “[t]he Commission did not grant” Nested Bean’s retraction request, “and it did not deny it.” *Pub. Citizen*, 508 F.3d at 1132. Because “the Commission took no action in this case,” *id.* at 1132, the deadlocked vote cannot give rise to an APA claim.

Even had the Commission denied Nested Bean’s retraction request, that *still* would not be final agency action subject to review. In *Aerosource*, the Third Circuit held that FAA’s denial of requests to retract agency reports was not final action. 142 F.3d at 580. Just like the agency’s original reports, the denials “did not impose an obligation, deny a right, or fix some relationship.” *Id.* The court emphasized that “treat[ing] the denial of an application to reconsider . . . as a final order” would allow a petitioner to “convert” the nonfinal FAA reports into a final agency action “simply by asking for reconsideration.” *Id.* at 579. “Of course,” the Third Circuit concluded, “this conversion should not be permitted.” *Id.*

Aerosource is directly on point. “The only thing” that Nested Bean could have been “denied” was “the ‘right’ to the” retraction of statements by CPSC and former Commissioner Trumka. 142 F.3d at 580. But the deadlock “did not require [Nested

Bean] to do anything, and there is nothing” from the vote “with which [Nested Bean] is expected to comply.” *Id.* “Thus,” CPSC’s response to the retraction request “no more imposed legal obligations, fixed rights, or altered a legal relationship than did the” underlying statements “themselves.” *Id.* at 581. Therefore, the deadlocked vote does not satisfy *Bennett* prong two and is not itself final agency action.

B. Counts I and V do not plausibly allege that CPSC exceeded its authority or failed to observe procedures required by law

Even apart from the lack of final agency action, Nested Bean’s overlapping challenges in Counts I and V fail to state a plausible APA claim. Counts I and V allege that CPSC’s safe sleep guidance was issued “not in accordance with law,” “in excess of” statutory authority, and “without observance of procedure required by law.” Compl. ¶¶ 104, 117, 158-63 (quoting 5 U.S.C. § 706(2)(A), (C), (D)). Count I raises similar challenges to the deadlocked vote. *Id.* ¶¶ 104, 117. These assertions do not withstand scrutiny.

1. Congress charged CPSC with, among other things, “protect[ing] the public against unreasonable risks of injury associated with consumer products” and “assist[ing] consumers in evaluating the comparative safety of consumer products.” 15 U.S.C. § 2051(b)(1)-(2); *see id.* § 2053. Congress therefore “gave the Commission broad powers to gather, analyze, and disseminate vast amounts of private information.” *GTE Sylvania*, 447 U.S. at 111. Those “powers include the authority to collect and disseminate product safety information.” *Id.* at 104 (citing 15 U.S.C. § 2054(a)(1)).

For example, CPSC must “collect, investigate, analyze, and disseminate injury data, and information, relating to the causes and prevention of death, injury, and illness associated with consumer products.” 15 U.S.C. § 2054(a)(1). And when it imposed various requirements on CPSC’s public disclosure of “information that reflects on the safety of a consumer product or class of consumer products,” Congress necessarily recognized that CPSC has authority to make such disclosures, and that it may do so subject to statutory requirements. *See id.* § 2055(b)(6). Moreover, like all federal agencies, CPSC also has inherent authority to communicate information to the public. *See Shurtleff v. City of Boston*, 596 U.S. 243, 251 (2022) (“When the government wishes to state an opinion, to speak for the community, to formulate policies, or to implement programs, it naturally chooses what to say and what not to say. That must be true for government to work.”); *cf. Barr v. Matteo*, 360 U.S. 564, 574-75 (1959) (plurality opinion) (finding implicit authority for public officials to make a “public statement of agency policy in respect to matters of wide public interest and concern”).

CPSC’s safe sleep guidance plainly falls within these broad authorities. Weighted baby blankets and weighted swaddles are “consumer products” under 15 U.S.C. § 2052(a)(5). And the guidance conveys safety information about those products and how to reduce the risk of injury to babies from consumer products in their sleep space. *See* Compl. ¶ 78.

2. Ignoring these ample statutory authorities, Nested Bean suggests the agency failed to comply with APA notice-and-comment requirements for rulemaking, Compl. ¶¶ 142, 163, and CPSA requirements for promulgating a mandatory safety

standard, *id.* ¶¶ 106, 108, 110-11 (citing 15 U.S.C. §§ 2056(a), 2058), banning hazardous products, *id.* ¶¶ 107-08, 112 (citing 15 U.S.C. § 2057), and establishing internal agency procedures, *id.* ¶ 109 (citing 15 U.S.C. § 2055). But CPSC’s safe sleep guidance was not a regulation and “do[es] not have the force and effect of law,” so the APA’s “notice-and-comment requirement ‘does not apply.’” *Perez v. Mortg. Bankers Ass’n*, 575 U.S. 92, 96 (2015) (quoting 5 U.S.C. § 553(b)(A)). Similarly, Nested Bean concedes that CPSC’s guidance was not a mandatory safety standard or hazardous product ban, *see* Compl. ¶¶ 4, 73, which renders 15 U.S.C. §§ 2057 and 2058 irrelevant.

Nested Bean also does not plausibly assert a violation of the one statute — 15 U.S.C. § 2055(b)(6) — that does apply here. Section 2055(b)(6) requires CPSC to “establish procedures designed to ensure that” information it discloses reflecting on the safety of a consumer product “is accurate and not misleading.” Congress explained that this “requirement is solely a direction to the Commission to establish internal clearance procedures.” *Danara Int’l, Ltd. v. CPSC*, 549 F. Supp. 367, 375 (D.N.J. 1982) (quoting H.R. Rep. No. 97-208, *as reprinted in* 1981 U.S.C.C.A.N. 1010, 1242). CPSC did so in Directive 1450.2, *see* 16 C.F.R. § 1101.1(c), and Nested Bean does not contend that the procedures in Directive 1450.2 are deficient in any way. It is thus undisputed “that the procedures . . . meet the requirements of the statute.” *Danara*, 549 F. Supp. at 375.

Nested Bean offers *no* support for its vague and conclusory allegation that “[t]he Commission took none of the required steps before it” issued the safe sleep guidance. Compl. ¶ 115. Nor does it suggest the Commission violated 15 U.S.C. § 2055(b)(6) specifically. Absent any well-pleaded allegations, Nested Bean cannot overcome the

“presumption of regularity [that] attaches to the actions of Government agencies.” *U.S. Postal Serv. v. Gregory*, 534 U.S. 1, 10 (2001). Accordingly, Count I fails as to the CPSC guidance, and Count V fails in its entirety.

3. Count I further fails to plausibly allege that the Commission’s deadlocked vote exceeded the agency’s authority. *See* Compl. ¶ 118. The CPSA expressly provides for the Commission to find whether “to publish a retraction of” information alleged to be “inaccurate or misleading.” 15 U.S.C. § 2055(b)(7). That authority plainly encompasses the Commission’s vote on Nested Bean’s retraction request. Nested Bean offers *no* explanation why this vote purportedly exceeds the Commission’s powers, and the Complaint’s “labels and conclusions” are insufficient to state a plausible claim. *Iqbal*, 556 U.S. at 678. The Court should dismiss Count I.

C. Count IV does not plausibly allege that CPSC acted arbitrarily or capriciously

Count IV asserts that the Commission’s deadlocked vote on Nested Bean’s retraction request and CPSC’s safe sleep guidance were “arbitrary and capricious” under the APA. Compl. ¶¶ 145-57 (citing 5 U.S.C. § 706(2)(A)). As to the deadlocked vote, Nested Bean alleges (i) the vote was “irreconcilable” with the Commission’s November 2023 “decision to *not* initiate [a] mandatory safety standards [rulemaking],” and (ii) the Commission did not explain this change or why it “denied” Nested Bean’s retraction request. *Id.* ¶¶ 149, 153-57. But the Commission’s deadlocked vote did not take any action on Nested Bean’s retraction request, *see supra* Part I.A.2, so there was no decision to explain, *see Sprint Nextel*, 508 F.3d at 1132, and no possibility that the

deadlocked vote “changed existing policy” or was “inconsistent[] with an earlier position,” *FDA v. Wages & White Lion Invs., LLC*, 145 S. Ct. 898, 918 (2025) (quotations omitted). Similarly, the Commission’s vote did not “revers[e]” or “disavow[] as no longer good law” its November 2023 decision not to adopt an amendment requiring agency staff to pursue a rulemaking. *Id.*

Next, Count IV offers conclusory allegations that CPSC failed to engage in “reasoned decision-making” when it issued its safe sleep guidance. *See* Compl. ¶ 152. Noting that CPSC based its guidance “on information from [CDC] and [NIH],” Nested Bean alleges that CPSC “has not conducted its own research or made its own determination as to the safety of [weighted infant sleep] products.” *Id.* ¶ 78. But the Complaint disproves that assertion. The Complaint states that CPSC staff “undertook a market scan of non-weighted wearable blankets and swaddles as well as a range of products marketed as weighted and made comparisons between the two groups.” *Id.* ¶ 77 (citations and quotations omitted). Also, CPSC “staff measured a variety of [weighted and unweighted] wearable blankets and swaddles” and made findings regarding “differences in the weight concentration.” *Id.* And the Complaint explains that CPSC staff regularly “reviewed and provided feedback on” draft standards prepared by an ASTM International subcommittee.⁷ *Id.* ¶¶ 72, 76-77. The Complaint thus shows that CPSC has conducted its own research and evaluation of weighted infant sleep products.

⁷ ASTM is an organization that develops and publishes voluntary consensus technical standards for a wide range of products and materials. *See* Compl. ¶ 51.

Nested Bean also errs in suggesting that CPSC could not reasonably cite the statements made by CDC and NIH. *Id.* ¶ 78. As detailed in Part II below, CDC and NIH are, like CPSC, charged with protecting the public health, and they have clear statutory authority to make their statements. They are also CPSC’s partners in the Safe to Sleep campaign, a collaborative effort between federal agencies and other organizations to promote safety recommendations to reduce the risk of SIDS, and they made their statements as part of that campaign.⁸ CDC’s and NIH’s statements about the safety of infant sleep products complement CPSC’s own efforts and information. Accordingly, Nested Bean has not plausibly shown that it was unreasonable for CPSC to cite CDC’s and NIH’s statements.

Furthermore, the Complaint does not plausibly allege there was “evidence before the agency” that contradicted CPSC’s guidance or required its retraction. Compl. ¶ 151 (quoting *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Nested Bean notes that CPSC has not adopted voluntary or mandatory standards for weighted infant sleep products and has indicated that adoption of such standards would require additional research. *See* Compl. ¶¶ 72-77. But the evidentiary requirements for issuing non-binding statements are far different from those for imposing nationwide industry standards. *Compare* 15 U.S.C. § 2055(b)(6) (requiring “procedures designed to ensure that [public statements are] accurate and not misleading”), *with id.* § 2058(f) (specifying findings required to promulgate a “consumer

⁸ *See, e.g.*, <https://perma.cc/8KG9-DM53>.

product safety rule”); *Finnbin, LLC v. CPSC*, 45 F.4th 127, 132 (D.C. Cir. 2017) (CPSA rulemakings require “a host of findings about costs and benefits”). The two situations involve wholly different considerations. Because Nested Bean has not plausibly alleged that the deadlocked vote or safe sleep guidance were arbitrary or capricious, Count IV should be dismissed.

II. Count II does not plausibly allege that NIH and CDC acted *ultra vires*

Count II alleges that NIH’s and CDC’s statements regarding weighted infant sleep products were *ultra vires*. Compl. ¶¶ 119-32. “*Ultra vires* review,” however, is “unavailable if . . . a statutory review scheme provides aggrieved persons with a meaningful and adequate opportunity for review.” *NRC v. Texas*, 605 U.S. 665, 681 (2025) (quotations omitted). Here, Nested Bean asserts that NIH’s and CDC’s statements “are final agency actions subject to judicial review.” Compl. ¶ 130. Assuming *arguendo* that this legal conclusion is correct, the APA would provide Nested Bean with a “meaningful and adequate opportunity for review,” and therefore *ultra vires* review would be “unavailable.” *Texas*, 605 U.S. at 681.

Even if *ultra vires* review were available, Nested Bean would have to show that NIH and CDC took “action entirely in excess of [their] delegated powers and contrary to a *specific prohibition* in a statute.” *Id.* (quotations omitted). In other words, *ultra vires* review has an “extremely limited scope.” *Changji Esquel Textile Co. v. Raimondo*, 40 F.4th 716, 721-22 (D.C. Cir. 2022) (quotations omitted). It is “confined to extreme agency error where the agency has stepped so plainly beyond the bounds of [its statutory authority], or acted so clearly in defiance of it, as to warrant the immediate intervention of an

equity court.” *Fed. Express Corp. v. U.S. Dep’t of Com.*, 39 F.4th 756, 764 (D.C. Cir. 2022) (quotations omitted). “Only error that is patently a misconstruction of [statute], that disregard[s] a specific and unambiguous statutory directive, or that violate[s] some specific command of a statute will support relief.” *Id.* (quotations omitted). For these reasons, the Supreme Court recently described *ultra vires* challenges as “essentially a Hail Mary pass – and in court as in football, the attempt rarely succeeds.” *Texas*, 605 U.S. at 681-82.

Nested Bean has not come close to meeting the demanding *ultra vires* standard because NIH and CDC acted pursuant to clear statutory authority. The Public Health Service Act expressly authorizes HHS and its subagencies to “disseminat[e] information to educate the public, health care providers, and other stakeholders on . . . sudden unexpected infant death.” 42 U.S.C. § 300c-13(a)(2). The agencies also may “develop, support, or maintain programs or activities to address sudden unexpected infant death.” *Id.* § 300c-11(a). In addition, they have broad authority to “conduct . . . such activities as may be required to make information respecting health information and health promotion . . . available to the consumers of medical care . . . and others who are or should be informed respecting such matters,” with such activities including “[t]he publication of information” about topics such as “child care” and “safety and accident prevention.” *Id.* § 300u-3(1). These statutes plainly authorize NIH’s and CDC’s

statements about the risks posed by weighted infant sleep products. *See* NIH, *Safe Sleep Environment for Baby*⁹; CDC, *Helping Babies Sleep Safely*.¹⁰

HHS and its subagencies also have authority to “encourage, cooperate with, and render assistance to . . . , and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes . . . and prevention of physical and mental diseases.” 42 U.S.C. § 241(a). They are further authorized to “collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities.” *Id.* § 241(a)(1). This statute further authorizes NIH’s and CDC’s challenged statements because the statements are “information as to, and the practical application of,” the American Academy of Pediatrics’ (“AAP”) evidence-based recommendations to reduce the risk of sleep-related infant deaths. *Id.* As the Safe to Sleep website explains, “the safe sleep messages outlined in Safe to Sleep® materials are based on recommendations from the AAP Task Force on SIDS.” Safe to Sleep, *Collaborators & Partners*;¹¹ *see* CDC, *Helping Babies Sleep Safely*. Finally, like all federal agencies, NIH and CDC have inherent authority to communicate information to the public. *See supra* Part I.B.1.

Nested Bean has not plausibly alleged that NIH or CDC “has taken action entirely in excess of its delegated powers and contrary to a *specific prohibition* in a statute.” *Texas*, 605 U.S. at 681.

⁹ <https://perma.cc/8KG9-DM53>.

¹⁰ <https://perma.cc/5JDC-K8P5>.

¹¹ <https://perma.cc/5RNP-RF4P>.

III. Count III does not plausibly allege that former Commissioner Trumka acted *ultra vires*

In Count III, Nested Bean attacks former Commissioner Trumka's statements as *ultra vires* in four respects, but each argument fails. *First*, the Complaint's allegation that Commissioner Trumka unlawfully "determine[d] that a product presents an unreasonable risk of injury," Compl. ¶ 143, is refuted by Nested Bean's concession that CPSC has not adopted any "mandatory product safety standards" or product "ban" containing such a determination, *id.* ¶¶ 4, 73. *Second*, Nested Bean's assertion that an individual Commissioner cannot "advocate" for a particular outcome, *id.* ¶ 143, ignores the principle that "[a] government official can share her views freely and . . . do so forcefully in the hopes of persuading others to follow her lead." *Nat'l Rifle Ass'n of Am. v. Vullo*, 602 U.S. 175, 188 (2024). *Third*, because CPSC's guidance was not itself *ultra vires*, former Commissioner Trumka did not step "plainly beyond the bounds of" his authority, *Fed. Express*, 39 F.4th at 764, by merely "repeat[ing]" that guidance, Compl. ¶ 143.

Finally, Nested Bean erroneously implies that former Commissioner Trumka's statements violated 15 U.S.C. § 2055(b)(1) because they enabled "the public [to] readily . . . ascertain Nested Bean's identity, without providing [the company with] advance notice and [an] opportunity to respond." Compl. ¶ 144. But these requirements apply only when the public can readily ascertain the identity of a manufacturer from "the manner in which [a] consumer product is to be designated or described" in information "public[ly] disclos[ed]" by a Commissioner. 15 U.S.C. § 2055(b)(1). Fatally, Nested Bean

does not allege that former Commissioner Trumka's statements *themselves* referenced the company, only that certain of his statements "cited" a Washington Post article, which in turn cited Nested Bean. Compl. ¶¶ 80-81. That is insufficient to state a violation of 15 U.S.C. § 2055(b)(1). At most, former Commissioner Trumka publicly disclosed his own statements, not the content of a Washington Post article.

CPSC's own regulations state that 15 U.S.C. § 2055(b)(1) "appl[ies] only when a reasonable person receiving the information in the form in which it is to be disclosed and lacking specialized expertise can readily ascertain *from the information itself* the identity of the manufacturer." 16 C.F.R. § 1101.13 (emphasis added). In applying this regulation, CPSC "staff will not . . . customarily perform research or look beyond the face of the document to determine whether the identity of a manufacturer can be ascertained." 48 Fed. Reg. at 57,409. Here, Nested Bean does not allege that its identity was ascertainable from "the face of" former Commissioner Trumka's statements. In short, Commissioner Trumka did not violate 15 U.S.C. § 2055(b)(1), let alone commit an "extreme agency error" involving an "unambiguous" violation of statute. *Fed. Express*, 39 F.4th at 764. Thus, Count III fails to state an *ultra vires* claim.

IV. Count VI fails for lack of subject-matter jurisdiction and a plausible due process violation

Count VI asserts a due process claim based on bias, alleging that former Commissioner Trumka "has strong negative opinions [about weighted infant sleep] products . . . and is incapable of neutral unbiased actions concerning these products in the future." Compl. ¶¶ 164-75. Because "standing is not dispensed in gross," Nested

Bean separately “must demonstrate standing for each claim that [it] press[es] and for each form of relief that [it] seek[s].” *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021). Nested Bean lacks standing to press this claim because it has not plausibly alleged any injury in fact. Rather, Nested Bean offers speculation about “actions concerning [weighted infant sleep] products in the future.” Compl. ¶ 175. But “threatened injury [must be] *certainly impending* to constitute injury in fact,” so Nested Bean’s “[a]llegations of *possible* future injury are not sufficient” for standing. *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 409 (2013).¹²

In any event, even if Nested Bean had standing when it filed suit, any claim is now moot. In July 2025, President Trump removed Commissioner Trumka from office, and the Supreme Court denied Commissioner Trumka’s request for immediate reinstatement. *See Boyle*, 145 S. Ct. at 2654; *Trump v. Wilcox*, 145 S. Ct. 1415 (2025). Because the issue of former Commissioner Trumka’s potential bias is “no longer ‘live,’” Count VI is moot. *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013).

Nested Bean’s due process claim also does not survive Rule 12(b)(6). Glaringly, Nested Bean does not allege that it is being deprived, or will imminently be deprived, of “life, liberty, or property” without due process. U.S. Const., amend. V; *see* Compl. ¶¶ 164-75. Moreover, Nested Bean’s due process theory requires that “a disinterested observer may conclude that [the decisionmaker] has in some measure adjudged the

¹² In addition, to the extent Count VI asserts a claim based on future agency rulemaking, *see* Compl. ¶ 175 & p. 44, the Court lacks jurisdiction also because the CPSA vests the courts of appeals with jurisdiction to review challenges to CPSC rules. *See* 15 U.S.C. § 2060; *see also Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 212-13 (1994).

facts as well as the law of a particular case in advance of hearing it.” *Metro. Council of NAACP Branches v. FCC*, 46 F.3d 1154, 1164-65 (D.C. Cir. 1995) (quotations omitted).

That showing is not made here because there was no “particular case” pending before Commissioner Trumka when he issued his statements and, given his removal, there will not be a future case before him. Count VI should be dismissed.

V. Count VII does not allege that the CPSC’s removal protections harmed Nested Bean

Count VII asserts that the for-cause removal protection for CPSC Commissioners in 15 U.S.C. § 2053(a) violates the separation of powers. Compl. ¶¶ 207-11. However, under *Collins v. Yellen*, 594 U.S. 220, 259-60 (2021), Nested Bean must show that the removal protection caused it compensable harm. The Complaint does not even *attempt* to show that the removal protections had any effect on the challenged actions. All the relevant events—CPSC’s safe sleep guidance, Commissioner Trumka’s statements, and the Commission’s vote on retraction—took place during former President Biden’s term in office, and Nested Bean does not contend that President Biden wanted to but could not remove any Commissioner.

Moreover, President Trump has since removed three Commissioners, and they have not served in those posts since approximately July 23, 2025. *See Boyle*, 145 S. Ct. at 2654. “[T]he very fact that President Trump removed [the Commissioners] disproves that the President had a perceived inability to remove the actor due to the infirm provision.” *Asbury Auto. Grp., Inc. v. FTC*, No. 4:24-cv-950-O, 2025 WL 2317455, at *6 (N.D. Tex. Aug. 11, 2025) (citation and quotation omitted). Therefore, Nested Bean has

failed to show that the “removal provisions actually impacted, or will impact, the actions taken by the CPSC against it.” *Leachco, Inc. v. CPSC*, 103 F.4th 748, 757 (10th Cir. 2024). Count VII should be dismissed.

CONCLUSION

For the foregoing reasons, the Court should dismiss the Complaint for lack of subject-matter jurisdiction and failure to state a claim.

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